# OFFICE OF REGULATORY AFFAIRS

# DIVISION OF IMPORT OPERATIONS AND POLICY

# GUIDANCE

# REGULATORY PROCEDURES MANUAL

# CHAPTER 9

# SUBCHAPTER IMPORT FOR EXPORT

Comments and suggestions regarding this document should be submitted to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact Joseph McCallion at 301-443-6553.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Office of Regulatory Affairs**
**September 2002**

**RPM Chapter 9, Subchapter Import for Export**
**SUBCHAPTER**
**IMPORT FOR EXPORT**

**This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.**

## PURPOSE

This subchapter is to provide guidance to FDA field offices regarding the handling of certain products that are offered for import under section 801 of the Federal Food, Drug, and Cosmetic Act (Act). Those products are those that are offered as "imports for export." The provision of the Act that permits such imports, section 801(d)(3), is referred to as the "import for export" provision. This guidance is intended to provide uniform procedures for handling such importations by all FDA offices. This chapter represents the Agency's current thinking on the application of the import for export provisions of the Act.

## BACKGROUND

The FDA Export Reform and Enhancement Act of 1996 (Export Reform Act), Public Law 104-134) amended section 801(d)(3) of the Act to allow the importation of certain articles that are unapproved or otherwise do not comply with the Act, provided that those imported articles are further processed or incorporated into products that will be exported from the United States, by their initial owner or consignee in accordance with section 801(e) or section 802 of the Act or section 351(h) of the Public Health Service Act (PHSA). On June 12, 2002, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), Public Law 107-188, was signed into law. Section 322 of PL 107-188 amended section 801(d)(3) of the Act. The amended provision is effective September 9, 2002.

Under the amended provision of the Act, importers wishing to import certain violative articles that are intended for further processing or incorporation into another product and subsequent export must provide FDA with certain information at the time of initial importation. The articles include drugs (or components), devices (or components or accessory of a device or other article of a device requiring further processing, which is ready or suitable for use for health-related purposes), food additives, color additives and dietary supplements. The information includes a statement that confirms the intent to further process such article or incorporate such article into a product to be exported and identifies entities in the chain of possession of the imported article. Importers also must provide certificates of analysis as necessary to identify the article unless the article is a device or an article described in section 801(d)(4). Section 801(d)(3)(A)(i)(III).

Under section 803(d)(3)(ii), at the time of initial importation and before delivery to the importer, initial owner, or consignee, a bond must be executed providing for liquidated damages in the event of default, in accordance with United States Customs Service (U.S. Customs) requirements.

The initial owner or consignee of the article must maintain records of the use and/or destruction of such imports and must submit the records or a report to FDA upon request. Section 801(d)(3)(A)(iv) and (v). The initial owner or consignee must destroy any article or portion not used in an exported product. Section 801(d)(3)(A)(iii).

The amended section 801(d)(3)(B) provides that FDA may refuse admission of an article that could otherwise be imported under section 801(d)(3)(A) if there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee or incorporated into a drug, biological product, device, food, food additive or dietary supplement that will be exported in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHSA.

The "import for export" requirements for blood, blood components, plasma, and source leukocytes differ from those for drugs and other biological products. The Act allows for the importation of these blood products and components provided they comply with section 351(a) of the PHSA or FDA permits such imports "under appropriate circumstances and conditions" as determined by the Center for Biologics Evaluation and Research (CBER) (section 801(d)(4) of the Act). Tissue products may be imported only if the importation complies with regulations promulgated under section 361 of the PHSA. The Bioterrorism Act did not amend section 801(d)(4). However, if CBER approves a particular request for import under section 801(d)(4), the import must comply with all applicable requirements of the amended section 801(d)(3) of the Act. Section 801(d)(4). The import also must comply with all applicable export requirements when the product is exported. Section 801(d)(3)(A)(i)(I) and (iii).

The Bioterrorism Act also amends section 301 of the Act. The amended section 301(w) prohibits the making of a knowingly false statement in any statement, certificate of analysis, record or report required under section 801(d)(3); the failure to submit a certificate of analysis; the failure to submit or maintain records; the release into interstate commerce of any article or portion imported into the United States under section 801(d)(3) or any finished product made from such article or portion, except for export in accordance with section 801(e) or section 802 of the Act, or section 351(h) of the PHSA; and, the failure to export or destroy any articles or portions not incorporated into a finished product. Section 801(d)(3) requires that the imported article or portions must be further processed or incorporated into a drug, biological product, device, food, food additive, color additive or dietary supplement that will be exported.

**GUIDANCE**

**INFORMATION SUBMISSION, ENTRY REVIEW, AND DOMESTIC FOLLOW-UP**

When a drug or device component, food additive, color additive, or dietary supplement is imported under section 801(d)(3), the importer is required to submit a statement to FDA at the time of each importation with the following information:

1. that such article (the components, parts, accessories, or articles) is intended to be further processed by the initial owner or consignee or incorporated by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported from the United States by the initial owner or consignee in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHSA; and
2. identification of the manufacturer of such article and each processor, packer, distributor or other entity that had possession of the article in the chain of possession from the manufacturer to such importer of the article.

The statement must be accompanied by such certificates of analysis as are necessary to identify such article unless the article is a device or is an article described in section 801(d)(4). Section 801(d)(3)(A)(i)(III).

In order for FDA to efficiently process such importations, the statement required to be provided to FDA pursuant to section 801(d)(3)(A)(i) must include, pursuant to that section, a declaration that the article is intended to be imported for further processing by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHSA. The statement should include information identifying the article and the initial owner or consignee.

Identification of all entities that had possession of the article in the chain of possession should include information sufficient to accurately identify the entity such as the name of each entity (including business and trade names), complete physical address, transaction dates, and any other information to aid in identification such as telephone and fax number, and e-mail address. The statement should include information sufficient to identify the chain of possession of the article through each entity, which could include information such as product coding, lot, batch, or other identification numbers. For medical devices, device history records required of domestic and foreign manufacturers, pursuant to 21 C.F.R. 820.184, may provide information to assist in meeting this requirement. For imported articles subject to section 801(d)(4), the manufacturer in the chain of possession can be considered to be the initial collection agency, e.g., a blood collection center for purposes of information required under section 801(d)(3).

Certificates of analysis, as are necessary to identify the imported article, must accompany the statement filed pursuant to 801(d)(3)(A)(i). Section 801(d)(3)(A)(i)(III). The submission of such certificates is not required if the imported article is a device or is an article described in 801(d)(4). Certificates of analysis, or equivalent documentation

should provide the article's formulation, ingredients, components, or assay, as appropriate to the type of article.

Certificates of analysis could include documents to assure the identity of the substance and its components in the chemical and drug industries. A batch certificate could be a certificate of analysis. A document that establishes a drug ingredient is certified to meet USP requirements could be a certificate of analysis. Documents that provide sufficient information to determine the level, potency, identity, strength, quality and purity of the drug component and whether prohibited material has been used in the imported article could be considered certificates of analysis.

For other products, documents that convey assurance as to the identity of the article and its components or substances could be a certificate of analysis. Sufficient information should be provided to determine if prohibited material has been used in the imported article. For an article of food additive or color additive, a document indicating specification of purity or documents establishing the article is a “certified” color or of “food grade” or “Codex Alimentarius” grade food additive could meet the requirement of a certificate of analysis.

When the initial owner or consignee of the imported article is not the importer, the importer should provide FDA with information identifying the initial owner or consignee with the entry. In cases where the importer is not the initial owner or consignee and the article is intended for multiple owners or consignees, each of whom will serve as the initial owner or consignee for a portion of the article, the importer should submit a separate statement identifying each owner or consignee and indicating the amount of the entry each is to receive. Failure to provide this information at the time of importation may be viewed by the district as evidence that the product does not meet the conditions of section 801(d)(3).

If the information needed to efficiently process importations and to make a “May Proceed” decision is not provided at the time the article is offered for entry, and if the product is otherwise subject to refusal of admission pursuant to section 801(a), the district may issue a Notice of Detention and Hearing in accordance with normal procedures (see RPM Chapter "Notice of Detention and Hearing"). If a response to the Notice of Detention and Hearing is not received by the district within the designated time (10 days, excluding Saturday, Sunday, and Holiday, or date requested by on the notice, or additional time as deemed necessary by the district), a Notice of Refusal should be issued (see RPM Chapter "Notice of Refusal of Admission" Guidance, "When Should the Notice of Refusal of Admission be Issued?"). Once issued, cancellation of the Notice of Refusal should be considered only under unusual circumstances at the discretion of the district (see RPM Chapter "Notice of Refusal of Admission" Guidance, "Reopening of a Case").

If the district has evidence or information indicating that the imported article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a product included in section 801(d)(3) that will be

exported in accordance with the Act or the PHSA, the district should contact the Division of Import Operations and Policy (HFC-170) before any action is taken on the entry. In certain circumstances, application of section 801(d)(3)(B)'s refusal authority may be appropriate.

**Submissions of Entries**

Entries of articles imported pursuant to section 801(d)(3) that are accomplished by electronic submission of information through the Customs Automated Commercial System (ACS) and the FDA Operational and Administrative System for Import Support (OASIS) will necessitate that the filer declare that the imported article is intended for further processing or incorporation into a product that will be exported in accordance with the Act. Section 801(d)(3)(A)(i). If the filer is not the "importer, initial owner or consignee" responsible for further processing or incorporating the imported article into the product to be exported, the filer of the entry should provide the name of such firm or individual in the FDA consignee field using the appropriate FDA Establishment Indicator (FEI) number. When the article is intended for multiple owners or consignees, a separate FDA line should be created for each owner or consignee as provided for in the ACS system. FDA has established an Affirmation of Compliance (AofC), identified by the code "IFE" (Import for Export), that will indicate that the entry is being made under the import for export provisions of the Act. Use of the "IFE" affirmation triggers prompts for the submission of Quantity and Value data. If any of this information is not provided, the notification will be considered incomplete by the system. Such lines with "IFE" (or any Affirmation) will display the Affirmation in the Entry Line Summary and line detail screen. If electronic submission is made, in most cases it is unlikely that all of the information required under section 801(d)(3) will be able to be provided through electronic entry. Districts should request and review the supporting paper entry documents for all "IFE" entries.

Once the district has determined that all of the appropriate information has been submitted, either by the on screen review process or by review of the entry documents, a "May Proceed" should be issued in accordance with OASIS procedures. The filer may be held responsible for the accuracy of the information provided through OASIS for such importations and import for export entries will be included in the FDA's filer evaluation conducted by the district of the broker.

For manual entry submissions, or when FDA has requested supporting paper entry documents for an electronic "IFE" entry, all documentation required by section 801(d)(3) should be included in the filer's entry package, including the statement and a certificate of analysis as necessary. When the imported article is intended for multiple owners or consignees, a separate statement and certificate of analysis as necessary should be submitted for each owner or consignee indicating the portion of the entry each is to receive. Districts should reconcile the quantities provided and any product not accounted for should be detained if otherwise subject to refusal of admission pursuant to section 801(a) as noted above. If the district determines that all information provided in the manual or electronic submission is appropriate, then the district should follow their normal procedures for marking the entry "May Proceed".

**Follow-up**
The district responsible for the entry review should use normal operating procedures to determine whether additional follow-up is necessary for entries made under section 801(d)(3). This can consist of additional contact with the importer or the initial owner/consignee at the time of entry to obtain records to confirm the intended use of the article and the final disposition of the article. The home district of the initial owner or consignee should be provided with a copy of the entry paperwork by the district performing the entry review (where the home district is not the importing district). Entries processed by OASIS will be available to home districts through a Sequel (SQL) report.

The imported article will continue to be subject to the U.S. Customs Temporary Import Bond or other bond instrument as required by U.S. Customs, under the new section 801(d)(3)(A)(ii) and remains subject to section 801(a). Any follow-up regulatory actions regarding the failure of the initial owner or consignee to meet the requirements of section 801(d)(3) should be referred to the Division of Import Operations and Policy (HFC-170) for handling.

When a domestic inspection is conducted at a manufacturer's facility where the imported article is being further processed or incorporated into a product intended for export, the inspection should include appropriate review of the domestic manufacturer's compliance with section 801(d)(3). For example, the investigator should request the manufacturer's import, export, and/or destruction records during an inspection. The records/reports should include documentation indicating that the imported article was further processed or incorporated into another product and was exported in accordance with section 801(e) or section 802 of the Act, or section 351(h) of the PHSA, or destroyed. The records should establish that the entire amount of the product or article imported is used or exported or destroyed; that the exported products are labeled in conformance with section 801(e)(1) and meet the other requirements of section 801(e)(1) or section 802 of the Act or section 351(h) of the PHSA, as appropriate. Please note, however, that for drug products, an initial owner or consignee may be allowed to retain a sample of the imported article in order to comply with good manufacturing process (GMP) regulations concerning sample retention.

**TIME FRAME FOR HOLDING IMPORTED PRODUCT**
Section 801(d)(3) allows for the importation of otherwise prohibited products and articles for manufacturing, further processing or incorporation and export. The amended provision does not impose any specific limitations on how long a product can be held in the United States before it must be further processed or incorporated into a product and exported or destroyed. A time limitation may be imposed, however, by Customs through its bond requirements.

**IMPORTED FOR FURTHER PROCESSING**
The legislative history of the Export Reform Act indicates that section 801(d)(3) was intended to allow manufacturing and processing activities not previously permitted under

the Act, and the legislative history of the Bioterrorism Act does not alter that intent. The terms "further processed" and "incorporated" can cover a wide range of activities. These can include packaging or labeling of finished products and specialized processing (such as sterilization) of a product. FDA recognizes that in some instances, it may be advantageous to manufacture a product in a foreign country and then ship it to the United States for specialized packaging or labeling. Merely storing an article or product in the United States before export is not considered "further processing."

**PRODUCTS SUBJECT TO DETENTION WITHOUT PHYSICAL EXAMINATION**

The import for export provision does not preclude the importation of articles that otherwise would be subject to detention without physical examination based on an FDA examination of previous shipments or a foreign inspection that documented significant good manufacturing practice (GMP) violations, or manufactured by a foreign firm that has refused to permit an FDA GMP inspection [21 CFR 820.1(d)]. Therefore, if these articles are offered for import in compliance with section 801(d)(3) or (4) such articles generally could be allowed unless other grounds exist for refusal of admission. Further guidance on criteria for accepting products for IFE that would otherwise be detained without physical examination products may be issued by each Center.

**COMPLIANCE WITH RELEVANT EXPORT PROVISIONS**

At the time of importation, FDA ordinarily will not know if the finished product will be exported under the provisions of section 801(e)(1) or section 802 of the Act or section 351(h) of the PHSA. Importers, initial owners, and consignees of articles imported or offered for import pursuant to section 801(d)(3) or (4) should determine whether the intended finished product meets the requirements of one or more of the export provisions (section 801(e)(1) and section 802 of the Act and section 351(h) of the PHSA). If they do not meet such requirements, they must destroy any products that may not be legally exported under the Act or the PHSA, as applicable. Section 801(d)(3)(A)(i)(I) and (iii).

**IMPORTATION OF FINISHED GOODS FOR STORAGE AND EXPORT WITHOUT FURTHER PROCESSING AND OTHER ARTICLES NOT INCLUDED UNDER SECTION 801(d)(3)**

Products and articles imported under section 801(d)(3) must be furthered processed or incorporated into a drug, biological product, device, food, food additive, color additive or dietary supplement that will be exported from the United States. This provision does not allow the import of violative products intended only for storage.

Importers of electronic products subject to performance standards are required by U.S. Customs regulation, 19 CFR 12.91, to file the form FDA 2877. Block A.7 on form FDA 2877 needs to be checked to indicate that the device is for medical device processing under import for export.

Since the wording of the amended section 801(d)(3) specifically identifies only food additives, color additives, and dietary supplements as the only food articles that can be imported for export, districts should not accept notification of import for export of other

foods that do not meet the criteria of a food additive, color additive, or dietary supplement. Similarly, cosmetics, as defined by section 201(i) of the Act, do not meet the criteria for import for export under the provisions of section 801(d)(3) and any offers for entry for such importations should be refused admission as appropriate.

The amended section 801(d)(3) also identifies specific products into which articles imported pursuant to the section can be incorporated for export. These are drugs, biological products, devices, foods, food additives, color additives, and dietary supplements. Cosmetics are not listed as a product that falls within this provision. Therefore, violative color additives intended for processing into a cosmetic product do not fall within the scope of section 801(d)(3), and entries for such importations should be refused admission, as appropriate.

**IMPORTATION OF VIOLATIVE COMPONENTS FOR FURTHER PROCESSING INTO OTHER COMPONENTS AND UNFINISHED PRODUCTS**

Many manufacturers assemble their products in various stages. These manufacturing steps may include sending partially completed products to firms in the United States for further manufacturing or processing, but not into a finished product. Neither the statutory language of the amended section 801(d)(3) nor the legislative history of the Export Reform Act or the Bioterrorism Act require that violative components allowed to be imported must be incorporated into "finished products." Because components, or "subassemblies," are the finished product of the U.S. manufacturer (although not necessarily a consumer ready product) and would constitute a drug, biological product, device, food additive, color additive, or dietary supplement within the Act's meaning, the agency has concluded that articles imported for use in the manufacture of such products fall within the scope of the import for export provision. Therefore, such products are subject to the requirements of section 801(e) or section 802 of the Act or section 351(h) of the PHSA.

**IMPORT FOR EXPORT PROVISIONS FOR PRODUCTS MANUFACTURED IN FOREIGN TRADE ZONES**

Foreign Trade Zones are federally sanctioned sites that, only for tariff purposes, are considered outside of the "Customs territory" of the United States. Nevertheless, products stored or manufactured in a Foreign Trade Zone are within the territory of the United States for the purposes of the Act and are expected to meet the same requirements as other products regulated by FDA [see Compliance Policy Guides 110.600 "FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses, or on Bonded Carriers" (CPG 7150.14), and 110.200 "Export of FDA Regulated Products from U.S. Foreign Trade Zones" (CPG 7150.11)]. These include the requirements of section 801(d)(3) and section 801(d)(4).

**RECORDS AND INFORMATION TO BE PROVIDED TO FDA UPON REQUEST**

The new section 801(d)(3)(A)(iv) requires that the initial owner or consignee maintain records on the use or destruction of the imported articles or portions and to provide records when requested. The initial owner or consignee is also required to submit a report to FDA, upon request, that provides an accounting of the export or destruction of

such imported article or portions and the manner in which such owner or consignee complied with the requirements of section 801(d)(3). The records should include the statements and any certificates of analysis required to be submitted at the time of import as described above. Additional records could include documentation with more specific identification of the product such as Customs entry number, date, quantities, manufacturing process and controls and intent of the importation (i.e., further processing into product intended for exportation). Records on export or other disposition need to be retained (section 801(d)(3)(A)(iv)) and should include information such as quantity, dates, destination, shipping, means of destruction, and any records required under the export record keeping and notification regulation. (21 C.F.R. 1.101).

**AGENCY CONTACTS**

Questions regarding importation of specific products should be referred to the appropriate Center (e.g., biological products, tissues, and procedures for considering requests to import violative blood products under section 801(d)(4) should be referred to CBER, Office of Compliance and Biologics Quality, Division of Case Management, Biological Drug and Device Compliance Branch (HFM-624); unapproved drugs should be referred to the Center for Drug Evaluation and Research, Office of Compliance, or Division of Labeling and Non-Rx Drug Compliance, Import/Export International Drug Team (HFD-316); food additives and color additives should be referred to the Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Enforcement, Imports Branch (HFS-606); medical devices and radiation emitting electronic products or their components should be referred to the Center for Devices and Radiological Health, Office of Compliance, Division of Program Operations (HFZ-305); feed additives, veterinary medical devices, and unapproved animal drugs should be referred to the Center for Veterinary Medicine, Division of Compliance (HFV-230)).

Information concerning CBER's review of import for export requests under section 801(d)(4) (blood and blood products) is in CBER's SOPP 8503.2, available at www.fda.gov/cber/regsopp/85032.htm.

Questions regarding the procedures to be followed by districts or industry relating to interaction with Customs should be addressed to the Division of Import Operations and Policy (HFC-170) 301-443-6553.